



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/510,474

10/07/2004

Bernard Charles Sherman

2051-62

1542

23117 7590 03/28/2008
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

VU, JAKE MINH

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,474	Applicant(s) SHERMAN, BERNARD CHARLES	
	Examiner JAKE M. VU	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/7/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment and Information Disclosure Statement filed on 10/07/2004.

- Claims 1-27 are pending in the instant application.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on 04/09/2002. It is noted, however, that applicant has not filed a certified copy of the Canada 2379887 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 21, 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by MOSKOWITZ et al (WO 00/56328).

Applicant's claims are directed toward a composition comprising of: simvastatin and excipients, wherein the amount of lactose is zero and the amount of cellulose is more than 60%. Additional limitations include: free of lactose, magnesium stearate,

Art Unit: 1618

citric acid, ascorbic acid, and butylated hydroxyanisole; and produced by a dry-mix process.

MOSKOWITZ teaches a composition comprised of: simvastatin and excipients, wherein the amount of cellulose is more than 60% (see pg. 29, Example 3).

Note, MOSKOWITZ does not disclose lactose, magnesium stearate, citric acid, ascorbic acid, or butylated hydroxyanisole in the composition; thus, the composition is free of these excipients.

Note, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this instance, the patentability of Applicant's invention does not depend on the dry-mix process.

Claims 1-3, 5, 26, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by ALBERTS et al (US 5,376,383).

Applicant's claims are directed toward a composition comprising of: simvastatin and excipients, wherein the amount of lactose is less than 40%, the amount of cellulose is more than 40%, and is free of butylated hydroxyanisole.

ALBERTS teaches a composition comprised of: simvastatin and excipients, wherein the amount of lactose is about 32.5% and the amount of cellulose, such as

Avicel, which is microcrystalline cellulose, and Methocel, which is methyl cellulose, is about 56%, and is free of butylated hydroxyanisole (see col. 11 Example 14).

Claims 1-4 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by RORK et al (US 5,366,738).

RORK teaches a lactose-free composition comprised of: simvastatin; about 33% of Avicel, which is microcrystalline cellulose (see col. 12, Example 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over MULLER et al (US 6,962,940) in view of FREESE et al (US 2003/0171407), REDMON et al (WO 99/49857) and FOX et al (US 6,558,659).

Applicant's claims are directed to a lactose-free composition comprising of: simvastatin; cellulose is more than 60%; disintegrants, such as starch, crospovidone, sodium starch glycolate, and croscarmellose sodium; lubricants, such as zinc stearate or sodium stearyl fumarate; and is free of antioxidants, such as citric acid, ascorbic acid

Art Unit: 1618

and butylated hydroxyanisole. Additional limitation include: produced by dry-mix process.

MULLER teaches that lactose-free composition generally comprised of an active ingredient, binder/filler, and a lubricant. Preferred lactose-free dosage forms comprise an active ingredient, microcrystalline cellulose, pre-gelatinized starch, and magnesium (see col. 15, line 56-64). Additional disclosures include: an active agent such as lovastatin (see col. 12, line 25), which is an anti-cholesterol drug similar to simvastatin (see Applicant's specification at pg. 1, line 5-6); examples of lactose-free compositions comprised of fillers, such as 53.5 % of microcrystalline cellulose or starch, wherein the fillers is typically about 50-90% (see col. 17, line 43-52); a disintegrant, such as croscarmellose, and a lubricant, such as magnesium stearate (see col. 29-30, Examples V and VI); and produced by compression, which reads on dry-mix process (see col. 31, line 1); antioxidants, such as citric acid, ascorbic acid and butylated hydroxyanisole, are not added in these examples; disintegrants, such as crospovidone, sodium starch glycolate, and croscarmellose, may be used (see col. 18, line 10-16); other lubricants can also be used, such as zinc stearate or stearic acid (see col. 18, line 17-33).

MULLER does not specifically teach using active agents, such as simvastatin; lubricants, such as sodium stearyl fumarate; or keeping the composition free of magnesium stearate.

REDMON teaches a lactose-free composition comprised of an active agent, such as fluoxetine, wherein the amount of microcrystalline cellulose excipient is over 90%

Art Unit: 1618

(see pg. 37, Example 4). Additional disclosures include: pre-gelatinized starch (see pg. 35, Example 2), disintegrants, such as crospovidone, croscarmellose, and sodium starch glycolate (see pg. 22, line 25-33); lubricants, such as zinc stearate or stearic acid (see pg. 24, line 6-22).

FREESE teaches a lactose-free composition comprised of: simvastatin; 72.5% of microcrystalline cellulose and starch bulking agents, and a lubricant, such as magnesium stearate (see [0041]). Additional disclosure includes: the ingredients are pressed into tablets, which reads on dry-mix process.

FOX teaches a lactose-free composition comprised of: pravastatin, but can be replaced with simvastatin (see col. 13, Example 4 and col. 6, line 25-28); fillers, such as 29% of microcrystalline cellulose, disintegrants, such as crospovidone (see col. 13, Example 4); lubricants, such as magnesium stearate (see col. 13, Example 4) or stearic acid or sodium stearyl fumarate (see col. 10, line 5-8) wherein the amount of cellulose and disintegrants are over 95% (see col. 13, Example 4) and the amounts of disintegrants exceed 3 percent (see col. 13, Example 4).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate active agents, such as simvastatin; using lubricants, such as sodium stearyl fumarate instead of magnesium stearate; using over 60% of microcrystalline cellulose; using over 95% of excipients into FREESE's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because a lactose-free composition would prevent adverse effects in the lactose-intolerance population; additionally, these are commonly used amounts

Art Unit: 1618

and ingredients in compressed tablets of pharmaceutical drugs, and reasonably would have expected success because simvastatin and all these ingredients have been used widely and interchangeably in the pharmaceutical industry.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/

Jake M. Vu, PharmD, JD
Art Unit 1618